

Remarks

Claims 1-42 are pending, with Claims 1-14 and 17-21 having been rejected and Claims 15, 16 and 22-42 having been previously withdrawn.

Claims 15, 16, 22-42 have now been cancelled without prejudice, and new Claim 43 has been added, antecedent basis existing throughout the application and claims.

With regard to the rejection based on nonstatutory obviousness-type double patenting, it appears that the Examiner agrees that these rejections will be maintained and finally resolved at such point where there is an indication of allowable subject matter, at which time, Applicant will consider and file any terminal disclaimer that is deemed proper.

The rejections under Sections 102 and 103 based on Hustead et al. ('970) are respectfully traversed. As mentioned previously, the reference appears to be cited largely for teaching a pH of up to 8.0, in the course of providing local anesthetics. Though NaOH is mentioned in the reference, it is clearly used in a very different manner and for very different purposes than is presently described and claimed. In fact, the Na cation is described as one of many possible anions to be used as counter ions to preferred "painless electrolytes" such as chloride and acetate. OH, in turn, itself is merely part of the buffering system used to keep the composition at or near neutral pH (see, e.g., col. 3, lines 20-23). Clearly nothing in this reference teaches or suggests a composition having, *inter alia*, inorganic base, such as sodium hydroxide, in an amount sufficient to provide a pH of about 8.0-13.0 at the body surface during administration of the local anesthetic agent, and in turn, enhance the flux of the local anesthetic agent through the body surface without causing damage thereto.

The current Office Action addresses these distinctions by stating, *inter alia*, that "intended use" must result in a "structural difference". While reserving the right to rebut the Examiner's underlying position, Applicant has added new claim 43 in an effort to facilitate the prosecution of the application. It would appear that this claim, and if acceptable, others like it, provide ample specificity and are both appropriate and patentable under the circumstances.

Finally, the rejection under Section 103 based on Yamanaka et al. ('497) is respectfully traversed. Yamanaka et al. is cited for teaching a medicated plaster containing an active agent and a basic substance (e.g., sodium hydroxide or potassium hydroxide) to keep a pH of 7 or

higher. Yamanaka et al. describe three different combinations, all of which contain either an acid or an acid group (col. 8, lines 51-57). The reference itself states that the acid services to prevent the decline of medicine over time. Given that Yamanaka et al. require the presence of an acid to maintain the system during storage, there is nothing in the reference that suggests including an enhancing and a neutralizing amount of a hydroxide-releasing agent.

Applicant again traverses the rejection, and reserves the right to rebut each and every aspect underlying the Examiner's conclusion regarding the need for a "structural difference" between the claim and the art. Still, in the interest of facilitating the prosecution of this application, Applicant has added new claim 43 providing further attributes of the attributes of the composition, each of which serve to further distinguish the cited art.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested. The Commissioner is hereby authorized to charge any additional fees required to Deposit Account No. 061910.

Respectfully submitted,

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